EXPRESS MAIL NO. EV207711513US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Tony N. Frudakis *et al.*
Application No.	:	09/810,936
Filed	:	March 16, 2001
For	:	COMPOSITIONS AND METHODS FOR THE THERAPY AND DIAGNOSIS OF BREAST CANCER

Examiner	:	Cheyne D. Ly
Art Unit	:	1631
Docket No.	:	210121.419C11
Date	:	March 19, 2003

Commissioner for Patents
Washington, DC 20231

REPLY UNDER 37 C.F.R. § 1.111

Commissioner for Patents:

In response to the Office Action dated September 19, 2002, please extend the period of time for response three months, to expire on March 19, 2003. Enclosed are a Petition for an Extension of Time and the requisite fee.

REMARKS

Claims 1-4, 6-10 and 12-22 are pending in the application with claims 18-22 currently under examination. Claims 1-4, 6-10 and 12-17 have been withdrawn as being drawn to non-elected invention.

Formal Drawings

Enclosed herewith are 18 sheets of formal drawings representing Figures 1 - 24.

Priority

The Office has granted claims 18-22 a priority date of May 24, 2000, corresponding to U.S. Serial Number 09/577,505. Applicants believe that they have properly claimed priority for instant application, including claims 18-22, with the earliest priority date originating from U.S. Serial Number 08/585,392, filed January 11, 1996. Included in that application were antigens overexpressed in tumor tissue, B11Ag1 (SEQ ID NO:16), the clone name for B305D, being among those. Applicants also recognized that antibodies to such antigens would also be useful and enabling disclosure was included in that filing for making and using such antibodies. Applicants respectfully request that the Office reconsider the priority date established for claims 18-22.

Claims Rejected for Lack of Enablement Under 35 U.S.C. § 112, First Paragraph

Claims 18-22 stand rejected under 35 U.S.C. § 112, first paragraph, as subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Office asserts that the specification fails to support the claimed invention of an isolated antibody that specifically binds to B305D and also that there is no disclosure within the specification that would enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

Applicants respectfully traverse this rejection. The instant specification teaches preparation of antibodies. For example, page 56, at lines 9-24, provides that "antibodies can be prepared by any of a variety of techniques known to those of ordinary skill in the art." For example, the preparation methods discussed include, cell culture techniques, including generation of monoclonal antibodies, transfection of antibody genes into suitable cell hosts for recombinant antibodies. Also included are immunogens comprising a polypeptide for use in generating antibodies to the immunogen. Example 7 puts this teaching into practice to generate antibodies to breast tumor antigen B305D. Polyclonal antibodies were generated to breast tumor antigen B305D by first recombinantly expressing the B305D in an *E. coli* recombinant expression system as described in the paragraph bridging pages 105-106. The recombinantly expressed B305D was purified by anion exchange as described on page 106, at lines 15-21.

Purified B305D was combined with muramyldipeptide and used to immunize rabbits as described on page 106, at lines 22-26.

As used by Applicants, an antibody or antigen-binding fragment thereof, "specifically binds," "immunologically binds" and/or is "immunologically reactive" to a polypeptide of the invention if it reacts at a detectable level (within, for example, an ELISA assay) with the polypeptide, and does not react detectably with unrelated polypeptides under similar conditions (page 54, lines 12-20). Rabbit sera was generated from the above described rabbit immunizations and B305D polyclonal antibodies showed immunoreactivity to B305D polypeptides when analyzed using an ELISA assay, as described in the paragraph bridging pages 106 and 107. The disclosed antibodies specifically bind to B305D. The antibodies generated were then used for immunohistochemical analysis of B305D expression in breast cancer and normal breast specimens, as described in pages 107-109, confirming the expression of B305D in breast tumor tissues.

Applicants respectfully submit that one of ordinary skill in the art would appreciate that Applicant was in possession of antibodies that specifically bind to B305D and would find the specification adequately enables such an artisan to make and use Applicants' claimed invention. In light of the above comments, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

The Office also asserts that claims 19-21 lack enablement in that they are broadly drawn to an isolated antibody, or antigen binding fragment thereof, that binds to a polypeptide having an amino acid sequence 80%, 90% or 95% identical to the amino acid sequence of SEQ ID NO:304.

Applicants respectfully traverse this ground for rejection. Applicants provide instruction for determining the percent identity of a particular sequence to the disclosed sequences in Applicants' specification, for example at pages 28-30. Applicants also disclose various B305D antigens that would fall within the scope of the claims, see in particular pages 97-99. As discussed above, the skilled artisan would readily appreciate that assays (such as an ELISA), can be used to determine if a polypeptide specifically binds to an antibody and does not react detectably with unrelated polypeptides under similar conditions. Such an assay is exemplified in Example 7 of the specification. With such guidance, one of ordinary skill in the art would easily

be able to determine whether a particular antibody fell within the scope of Applicants' claimed invention without undue experimentation. Applicants respectfully submit that one of ordinary skill in the art would appreciate that Applicants were in possession of antibodies that specifically bind to polypeptides having amino acid sequences 80, 90 or 95% identical to the amino acid sequence of SEQ ID NO:304 and would find that the specification adequately enables such an artisan to make and use Applicants' claimed invention. In light of the above comments, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims Rejected Under 35 U.S.C. §102

Claims 18-22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Xu *et al.* US Patent No. 6,329,505. The Office points to Xu et al., column 66, lines 49-50 as disclosing an antibody against prostate-specific polypeptides wherein the said polypeptide is a splice form of B305D.

Applicants respectfully traverse this ground for rejection. As discussed above, Applicants believe that they have correctly claimed priority dating back to U.S. Serial Number 08/585,392, filed January 11, 1996. As such, US Patent No. 6,329,505 would not be considered art under 35 U.S.C. § 102(e). In light of the above comments, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e), is respectfully requested.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

Tony N. Frudakis *et al.*

SEED Intellectual Property Law Group PLLC

/Julie C. Lyell - 52,461/

Susan Lingenfelter, Patent Agent
Reg. No. 41,156

Enclosure:

Postcard
Formal Drawings (18 sheets, Figs. 1-24)

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031
D:\NrPortbl\iManage\JUDYD\366195_1.DOC